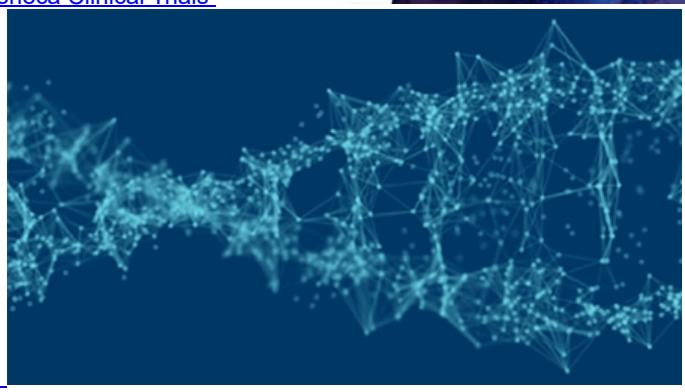
- Skip to content
- Skip to navigation
- Skip to footer

AstraZeneca

Search Enter your search

- What science can do
  What science can do
  - Stories of impact
  - Publications
- R&D
  R&D
  - Our approach
    Our approach to R&D
    - STEM at AstraZeneca
  - Precision medicine
  - Transformative science
  - Data science & AI
  - Clinical innovation
  - Our technologies
  - Next generation therapeutics
  - R&D strategic centres

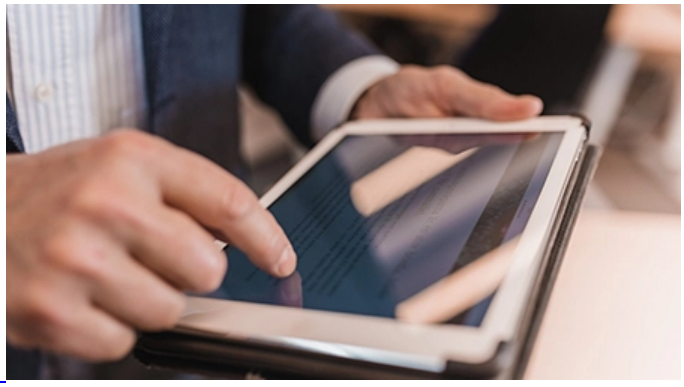
Featured website AstraZeneca Clinical Trials Featured website Open Innovation 

- Our therapy areas
  Our therapy areas
  - Oncology
  - BioPharmaceuticals
  - Cardiovascular, Renal and Metabolism
  - Respiratory & Immunology
  - Vaccines and Immune Therapies
  - Rare Disease
  - Pipeline
  - All medicines
- Our company
  Our company
  - Our history
  - Our people
    Our people
    - Oncology
    - BioPharmaceuticals
    - Rare Disease
    - Research & Development
    - Enabling functions

- Operations
- International
- Our leadership
- Cambridge
- Gothenburg
- Gaithersburg

- Careers
Careers
  - Great place to work
  - Inclusion and diversity
  - Learning and development
  - Employee resource groups
- Investors
Investor Relations (Global)
  - Investor Relations (Sweden)
  - Resources
  - Governance
  - Shareholder information
  - Dividend policy
  - Key facts
  - FAQs
  - Debt Investors
  - ADR Programme

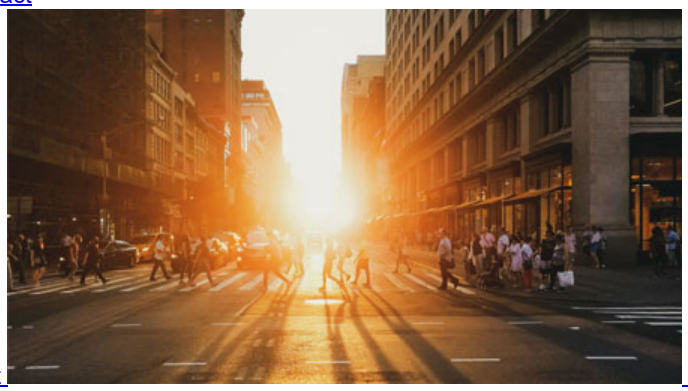
Feature Q1 2025 results



Feature Results and presentations
- Media
Media
  - Press Releases
  - Articles
  - Image library
  - Archive
  - Media contacts
  - Investor Day 2024
- Sustainability
Sustainability
  - Climate change

Climate change overview
- Renewables
- Product sustainability
- AZ Forest

- Nature
Nature overview
  - Water stewardship
  - Pharmaceuticals in the environment
  - Waste and circularity
- Health equity
Health equity overview
  - Science
  - Healthcare delivery
  - Community investment
- Health systems resilience
Health systems resilience overview
  - Partnership for Health System Sustainability and Resilience (PHSSR)
- Ethics and governance
Ethics and Compliance
  - Governance
  - Sustainability governance
- Our people
Great place to work
  - Inclusion and diversity
  - Learning and development
  - Workforce safety and health
- Our Values
- Partnerships and alliances
- Resources
Sustainability resources
  - Our sustainability impact



Feature Our sustainability impact Feature Sustainable science

- Partnering
Partnering
  - Our business development teams

Evusheld long-acting antibody combination approved in the EU for pre-exposure prophylaxis (prevention) of COVID-19 in a broad population

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Evusheld significantly reduced the risk of developing symptomatic COVID-19 in PROVENT Phase III trial, with protection lasting at least six months

Evusheld retains neutralising activity against the Omicron BA.2 subvariant, now the dominant strain in Europe

AstraZeneca's *Evusheld* (tixagevimab co-packaged with cilgavimab), a long-acting antibody combination, has been granted marketing authorisation in the European Union (EU) for the pre-exposure prophylaxis (prevention) of COVID-19 in a broad population of adults and adolescents aged 12 years and older weighing at least 40 kg.

The approval by the European Commission was based on results from the *Evusheld* clinical development programme, including data from the PROVENT Phase III pre-exposure prophylaxis trial which showed a 77% reduction in the risk of developing symptomatic COVID-19 compared to placebo at the primary analysis and an 83% reduction at a six-month median analysis, with protection from the virus lasting at least six months.[1-3] *Evusheld* was generally well-tolerated in the trial.[1-3]

Christoph D. Spinner, MD, Consulting Physician Infectious Diseases and Pandemic Officer at the University Hospital Rechts der Isar and adjunct teaching professor at the Technical University of Munich, Munich, Germany, said: “Increasing COVID-19 cases, driven by the highly-transmissible BA.2 subvariant, and withdrawal of several pandemic public health measures make it important to protect vulnerable populations, such as the immunocompromised, from SARS-CoV-2 infection. The authorisation of *Evusheld* for a broad population will allow health authorities in the EU to identify the populations who are most at-risk and need additional protection.”

Mene Pangalos, Executive Vice President, BioPharmaceuticals R&D, AstraZeneca, said: “The EU approval represents an important milestone in our efforts to help prevent COVID-19, and we will continue to work with governments across Europe to make *Evusheld* available as quickly as possible. *Evusheld* has the potential to provide long-lasting protection against COVID-19 for a broad population of individuals, including those who aren’t adequately protected by a COVID-19 vaccine, as well as those at increased risk of exposure.”

The recommended dose of *Evusheld* in Europe is 150mg of tixagevimab and 150mg of cilgavimab, administered as two separate sequential intramuscular (IM) injections.

There is a growing body of evidence from multiple independent in vitro and in vivo (animal model) studies supporting the potential of *Evusheld* to protect against the BA.1, BA.1.1 and BA.2 Omicron SARS-CoV-2 subvariants in circulation around the world.[4-6] New data from Washington University School of Medicine demonstrated *Evusheld* retained potent neutralising activity against the emerging and highly transmissible BA.2 subvariant, which is the dominant strain in many European countries and currently accounts for over 60% of COVID-19 infections in Europe.[6,7] This study also showed *Evusheld* reduced viral burden and limited inflammation in the lungs (in vivo) across all Omicron variants.[6]

Evusheld is authorised for emergency use for pre-exposure prophylaxis of COVID-19 in the US and has been granted conditional marketing authorisation by the Medicines and Healthcare products Regulatory Agency (MHRA) in Great Britain for pre-exposure prophylaxis of COVID-19. Additionally, there are a number of countries across Europe that have agreements in place to provide *Evusheld*.

People who are not adequately protected by a COVID-19 vaccine may particularly benefit from pre-exposure prophylaxis with *Evusheld*.[8-12] This population includes about three million people in the EU who are immunocompromised such as people with cancer or transplant patients or anyone taking immunosuppressive medicines.[13] People at increased risk of exposure to the SARS-CoV-2 virus could also benefit from protection with *Evusheld.*[14]

Evusheld is the only long-acting antibody combination with positive Phase III data in the prevention and treatment of COVID-19.[2,15] AstraZeneca is progressing with filings around the globe for potential emergency use authorisation or marketing approval of *Evusheld* in both COVID-19 prophylaxis and treatment.

Notes

Evusheld

Evusheld, formerly known as AZD7442, is a combination of two long-acting antibodies - tixagevimab (AZD8895) and cilgavimab (AZD1061) - derived from B-cells donated by convalescent patients after SARS-CoV-2 infection. Discovered by Vanderbilt University Medical Center and licensed to AstraZeneca in June 2020, the human monoclonal antibodies bind to distinct sites on the SARS-CoV-2 spike protein[16] and were optimised by AstraZeneca with half-life extension and reduction of Fc effector function. The half-life extension more than triples the durability of its action compared to conventional antibodies;[17-19] data from the PROVENT Phase III trial show protection lasting at least six months.[1,3] The reduced Fc effector function aims to minimise the risk of antibody-dependent enhancement of disease - a phenomenon in which virus-specific antibodies promote, rather than inhibit, infection and/or disease.[20]

Evusheld has been granted marketing authorisation in the European Union and Great Britain for pre-exposure prophylaxis (prevention) of COVID-19. In the United States, *Evusheld* is authorised for emergency use for pre-exposure prophylaxis of COVID-19 in people with moderate to severe immune compromise due to a medical condition or immunosuppressive medications and who may not mount an adequate immune response to COVID-19 vaccination, as well as those individuals for whom COVID-19 vaccination is not recommended due to a history of severe adverse reaction to a COVID-19 vaccine. This population includes people with blood cancers or other cancers being treated with chemotherapy, and those taking medications after an organ transplant or who are taking immunosuppressive drugs for conditions including multiple sclerosis and rheumatoid arthritis.[1] It is also authorised for use and being supplied in several other countries around the world.

The primary data supporting the *Evusheld* authorisations are from the ongoing PROVENT Phase III pre-exposure prevention trial, which showed a statistically significant reduction in the risk of developing symptomatic COVID-19 compared to placebo, with protection from the virus continuing for at least six months (77% at primary analysis [8/3441 (0.2%) *Evusheld* arm, 17/1731 (1.0%) placebo arm]; 83% at median six month analysis [11/3441 (0.3%) *Evusheld* arm, 31/1731 (1.8%) placebo arm]).[1-3] Follow-up is ongoing to establish the full duration of protection provided by *Evusheld*.

In October 2021, AstraZeneca announced positive high-level results from the TACKLE Phase III outpatient treatment trial in which a 600mg IM dose of *Evusheld* was generally well-tolerated. AstraZeneca is discussing the TACKLE mild-to-moderate COVID-19 treatment data with health authorities.

Evusheld was generally well-tolerated in the trials.

Evusheld is being developed with support from the US government, including federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority in partnership with the Department of Defense; Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense, under Contract No. W911QY-21-9-0001.

Under the terms of the licensing agreement with Vanderbilt, AstraZeneca will pay single-digit royalties on future net sales.

AstraZeneca

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Contacts

For details on how to contact the Investor Relations Team, please click here. For Media contacts, click here.

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